

PATENT/Docket No. PC10299A

Appl. No. 09/489,711

Filing Date: January 24, 2000

REMARKS

I. Preliminary Remarks

In the Office Action, Claims 13, 16, 17, 24-27, and 30-33 are pending and under examination. Claims 1-12, 14-15, 18-23, 28-29, and 34-39 are canceled. Claims 13, 16, 17, 24-27, and 30-33 are rejected.

After entry of this paper, Claims 1-16, 18-25, 28-29, and 33-39 are cancelled without prejudice in an effort to favorably advance prosecution of the present application. Applicants reserve the right to pursue the subject matter of the cancelled claims in a continuation application. Claims 17, 26-27, 30-32, and 40-41 are under consideration. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This response is timely filed with an extension of time for three months. The USPTO has been given authorization to charge Deposit Account No. 21-0718 for this fee and any other fees necessary with the submission of this response.

II. Patentability Arguments

A. The Rejection of Claims 17 and 30 under 35 U.S.C. §112, First Paragraph, May Properly Be Withdrawn.

Claims 17 and 30 and those dependent therefrom were rejected as containing new subject matter. The Examiner stated that these claims include the limitation: 'about 8% v/v of an amphiphilic surfactant' and this is not supported in the specification. Claims 17 and 30 have been amended to include the phrase 'and a combined volume of about 8% v/v of Tween 80 and Span 80 surfactants' (see listing of claims above), which renders this rejection moot. Support for this amendment is found on page 4, line 1. Withdrawal of this rejection is therefore respectfully requested.

The Examiner also stated that these claims include the recitation: 'wherein said vaccine composition protects an animal against *E. rhusiopathiae* infection' and this is not supported in

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the specification because the specification is limited to pigs, and 'an animal' is broader in scope. The Applicants respectfully traverse this rejection. Support for the term 'animal' is found on page 2, lines 3-4; page 3, lines 1-4, page 6, lines 11-20, and page 21. In view of the foregoing, Applicants respectfully submit that one skilled in the art can practice the claimed invention without undue experimentation. The rejection of Claims 17 and 30 and those dependent therefrom under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of this rejection is respectfully requested.

B. The Indefiniteness Rejections of Claims 25, 27, and 30-33 under 35 U.S.C. §112, Second Paragraph, May Properly Be Withdrawn.

The Examiner rejected claims 25, 27, and 30-33 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Applicants respectfully traverse this rejection.

(a) The Examiner states that Claim 31 is vague and confusing because it is unclear how the broader term 'immunity' in Claim 31 further limits the limitation 'protection' from Claim 30. Claim 31 has been amended to include the phrase 'and protects weaned pigs against *E. rhusiopathiae* infection' (see listing of claims above), which renders this rejection moot. Support for this amendment is found on page 21, Example 4. Withdrawal of this rejection is therefore respectfully requested.

(b) The Examiner states that Claim 25 is confusing and/or has improper antecedence in the limitation 'the concentrated composition' because it depends from Claim 24, which does not recite any 'concentrated' composition. Claim 25 has been cancelled (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.

(c) The Examiner states that an analogous criticism (as (b) above) applies to Claim 27. Claim 27 has been amended to depend from Claim 41 (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.
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(d) The Examiner states that Claim 30 has improper antecedence in the limitation 'the culture fluid fraction' because there is no earlier recitation of said phrase. Claim 30 has been

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amended to replace the term 'the culture' with the term 'said' (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.

(e) The Examiner states that Claim 30 is incorrect in reciting a comma after the limitation 'and,' in line 8 of the claim. Claim 30 has been amended to delete the comma (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.

(f) The Examiner states that Claims 31-33, which depend from Claim 30, are rejected as being indefinite because of indefiniteness or vagueness identified in the base claim. Claim 30 has been amended as described above (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.

In summary, for the foregoing reasons, Applicants respectfully submit that the rejection of claims 25, 27, and 30-33 for indefiniteness under 35 U.S.C. §112, second paragraph, may be properly withdrawn. Applicants respectfully requests withdrawal of this rejection.

C. The Anticipation Rejection of Claims 17, 24-27, and 30-33 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 17, 24-27, and 30-33 are rejected under 35 U.S.C. §102(b) as being anticipated by Frantz, *et al.*, (US 5,695,769) as evidenced by Barenholz, *et al.*, (US 6,156,337) and Zarkasie, *et al.*, (*J.Vet.Med.Sci.* 58:87-90, 1996).

A patent is invalid for anticipation under 35 USC 102(b) if a single prior art reference discloses each and every limitation of the invention as set forth in the claims. (*Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. Applicants respectfully submit that these criteria are not met in the Examiner's rejection.

In the instant Application, the vaccines are claimed to include an adjuvant, which comprises about 2% v/v lecithin, about 18% v/v mineral oil, and a combined volume of about 8% v/v of Tween 80 and Span 80 surfactants with the remaining volume being a saline solution (see Claims 17 and 30 and those dependent therefrom). Support for inclusion of these surfactants is found on page 4, line 1; page 7, lines 28-32; and page 12, lines 20-23. Applicants respectfully submit that Frantz *et al.* do not describe the inclusion of a surfactant in the vaccine compositions containing *E. rhusiopathiae*, and in particular do not include the surfactants Tween 80 and Span

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80. Frantz *et al.* reference a surfactant in Example 7 (Col 16, Lines 43-44 and Lines 53-55), where it is indicated that 0.1-0.3% Tween 80 was included in a seed medium for culturing *E. rhusiopathiae*. However, the Tween 80 would not be included in the final vaccine composition, and this volume of Tween 80 and Span 80 is substantially less than the volume claimed in the instant application. Also, Frantz *et al.* describe using Tween 80 and Span 80 in Example 9 (Col 19, Lines 38-39), where it is indicated that 2.8% Tween 80 and 1.2% Span 80 (total volume of 4%) are included in a combination vaccine. However, again this volume of Tween 80 and Span 80 is substantially less than the volume claimed in the instant application. In addition, the vaccine does not contain *E. rhusiopathiae*, as is also claimed in the instant application. Thus, Applicants respectfully submit that Frantz *et al.* do not teach a vaccine composition containing an inactivated *E. rhusiopathiae* fluid fraction with the specific adjuvant as presently claimed, i.e., an adjuvant with the specific amounts of specified ingredients as recited. Frantz *et al.* do not disclose each and every limitation of the invention as set forth in the claims

Finally, Claims 24, 25 and 33 have been cancelled (see listing of claims above), which renders this rejection moot in regard to these claims.

Thus, based on the remarks presented herein, the rejection of Claims 17, 24-27, and 30-33 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

D. The Obviousness Rejection of Claims 13 and 16 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantz, *et al.*, (US 5,695,769) in view of Applicants' admitted state of the art and Barenholz, *et al.*, (US 6,156,337). Applicants respectfully traverse this rejection.

Claims 13 and 16 have been cancelled (see listing of claims above), which renders this rejection moot. Withdrawal of the rejection is therefore respectfully requested.

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III. Conclusion.

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 17, 26-27, 30-32, and 40-41 are in condition for allowance and request expedited notification of same.

Respectfully submitted,



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